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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,323	03/20/2000	STEFAN SANNER	258.00040101	2155

7590 12/11/2001  
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EXAMINER
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BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	09/446,323		SANNER, STEFAN	
	Examiner		Art Unit	
	P. Kathryn Bex		1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 06 April 2000.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-3, 7, 8 and 10-12 is/are rejected.

7) ☒ Claim(s) 4-6 and 9 is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 20 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All    b) ☐ Some    \* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: #55 in any of the Figures, see page 6, end of paragraph 2; #10, Figures 2 or 3, see page 3, paragraph 6 and page 4, paragraph 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

2. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from the foreign document and are

replete with grammatical and idiomatic errors. Example of some unclear and indefinite terms used in the claims are:

Claim 1, lines 4 and 7, contain the phrase "in such a manner", it is vague and indefinite as to what Applicant means by such a limitation. In what *manner* is applicant referring to?

Penultimate line, the conditional phrase "can be" or "can additionally be" are not positive recitations, therefore, renders the claim indefinite. Same deficiency was found in claim 2, 8-9 and 11-12. } *manner*

Claim 2, line 3, the term "steep" is a relative term which renders the claim indefinite. The term "steep" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not definite as to what Applicant considers a "steep" thread.

Claim 3, line 1, "the sample facing end" lacks antecedent basis.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte*

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*Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation "joint", and the claim also recites "a film hinge" which is the narrower statement of the range/limitation.

Same claim, the term "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Same deficiency was found in claim 6.

Claim 5, line 1, "the two half-tubes" lacks antecedent basis. Examiner believes this claim should depend from claim 4.

Line 2, "its" is vague and indefinite as to what element it refers to.

Claim 9, "the cone-shaped ring", "the sieve" and "the indentation" both lack antecedent basis. Examiner believes this claim should depend from claim 6.

6. Applicant is required to review and correct these errors so that the claims conform with the U.S. patent practice.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 8, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Seymour (USP 5,393,496).

Seymour teaches a saliva sampling device which includes a sample-taking means 1113, a

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cartridge containing reagent, and a testing disks 1634, 1734. These elements are modularly coupled, wherein the sample mixture is brought into contact with the testing disks. Additionally, these elements are contained within a housing 1114, 1214 1714. Moreover, a plurality of such housings can be disposed within a kit (Figs. 58, 64-76). The sample-taking means comprising micro-porous chambers. Additionally, the sample-taking means comprising a thread which couples to a corresponding internal thread of the housing via the cartridge (Figs. 98-99, 107-108).

9. Claims 1-3, 8, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Seymour (EP 520,408 A2).

Seymour teaches a saliva sampling device which includes a sample-taking means 1913, a cartridge 1711, 1911, 2111 containing reagent and a testing disks (14) 1734. These elements are modularly coupled, wherein the sample mixture is brought into contact with the testing elements 1930. Additionally, these elements are contained within a housing 1114, 1214, 1714, 1914. The testing elements can be displaced after having been introduced into the housing. Moreover, a plurality of such housings can be disposed within a kit (Figs. 58, 64-76). The sample-taking means comprising micro-porous chambers. Additionally, the sample-taking means comprising a thread which couples to a corresponding internal thread of the housing via the cartridge.

10. Claims 1-3, 8, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (USP 4,770,853).

Bernstein discloses a device for self-contained solid phase immunodiffusion assay. The device comprising a housing 13 in which a cartridge 15, testing means 18 and sample taking means 2 are positioned. Additionally, the cartridge and testing means are displaceable within the

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housing such that the testing means is brought into contact with the sample mixture for analyzing this mixture. The sample-taking means comprising threads 18-19, 21 couples to corresponding internal thread, or nodule 4, of the housing (Figs. 1-6). Bernstein teaches the use of membranes 7 to contain the reagents.

11. Claims 1, 3, 7, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nason (USP 4,978,504).

Nason teaches a specimen test housing having a sample-taking means 12, a cartridge 30 containing reagent and a cylindrical testing means 70. The cartridge 30 contains filter members 18-19 which can be pre-impregnated with selected reagents (column 8, lines 9-14). The testing means can be placed into an appropriate optical detection device when the sample mixture is brought into contact with the testing means. The sample-taking means comprising micro-porous chambers. One end of the cartridge comprises an opening which can be closed by a valve 52' (Figs 17-19). Additionally, one or both of the filter plugs 18-19 may have hydrophobic characteristics to define a fluid seal.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (USP 4,770,853) in view of Berger (USP 4,269,237).

Bernstein as previously discussed above, does teach a rupturable membrane for controlling the flow of the material through the cartridge. However, Bernstein does not recite the specific use of a ball for closing the opening of a cartridge. However, the use of ball valves is considered conventional in the dispensing art, see Berger. Berger device for draining or collecting sump oil from a container, wherein the container has a drain plug closed by a ball valve or rupturable membrane (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have substituted the rupturable membrane means of Bernstein, with the ball valve, as taught by Berger. Ball valves are known within the art to provide reliable sealing which can be reused repeatedly.

#### ***Allowable Subject Matter***

15. Claims 4-6 and 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: the instant claims are drawn to a device for taking and examining samples. While numerous specimen test unit exist comprising a housing containing a sample-taking means, cartridge, and



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testing elements, none of the prior art teach the sample-taking means consisting of two half-tubes which are connected with each other by a joint or elastic web.

**Conclusion**

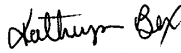
17. No claims allowed.


18. The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure are Phillips *et al* and Hounsell. They are cited of interest in that they show various embodiments of devices for collecting biological samples.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays from 6:00 am to 3:30 pm EST.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

  
P. Kathryn Bex  
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12/10/01

  
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